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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number	09/721,131
Filing Date	November 22, 2000
First Named Inventor	Bass, Ralph L.
Group Art Unit	36181616
Examiner Name	Frank Choi
Attorney Docket Number	014123-000008

ENCLOSURES (check all that apply)

- ☒ Fee Transmittal Form
  - ☒ Fee Attached
- ☐ Amendment / Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Documents
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☒ Appeal Communication to Group ***(Appeal Notice, Brief, Reply Brief)***
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below):*

**Appeal Brief*
**Acknowledgment Postcard*
**Check in the amount of $165.00*

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual Name	JENNIFER L. SKORD (REG NO. 30,687) MOORE & VAN ALLEN
Signature	Jennifer L. Skord
Date	JUNE 25, 2004

CERTIFICATE OF TRANSMISSION/MAILING

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 165.00

Complete if Known	
Application Number	09/721,131
Filing Date	November 22, 2000
First Named Inventor	Bass, Ralph L.
Examiner Name	Frank Choi
Art Unit	1616
Attorney Docket No.	014123-000008

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number	13-4365
Deposit Account Name	Moore & Van Allen, PLLC

The Director is authorized to: (*check all that apply*)

☐ Charge fee(s) indicated below ☒ Credit any overpayments

☐ Charge any additional fee(s) or any underpayment of fee(s)

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below	Fee Paid
Total Claims		-20**=		x	=	
Indep. Claims		-3** =		x	=	
Multiple Dependent					=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

***or number previously paid, if greater; For Reissues, see above.*

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge – late filing fee or oath	
1052	50	2052	25	Surcharge – late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examination action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	165.00
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,330	2453	665	Petition to revive – unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1406	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 165.00

SUBMITTED BY				Complete (*if applicable*)	
Name (Print/Type)	Jennifer L. Skord	*Registration No. (Attorney/Agent)*	30,687	*Telephone*	(919) 286-8000
Signature	Jennifer L. Skord			*Date*	06/25/2004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	:	Bass, Ralph L.	Confirmation No. 2281
Docket Number	:	014123-000008	
Application Number	:	**09/721,131**	
Art Unit	:	1616	
Filed	:	November 22, 2000	
Examiner	:	Frank Choi	
Title	:	METHOD FOR TREATING HIV	

Commissioner for Patents
Mail Stop Appeal
P.O. Box 1450
Alexandria, Virginia 22313-1450

APPEAL BRIEF UNDER 37 CFR 1.192

Sir:

This is an Appeal from the Final Rejection dated April 19, 2004. A Notice of Appeal was mailed June 2, 2004. Thus, the due date for filing the Appeal Brief is up to and including **August 2, 2004**.

This Appeal Brief and its attachment of the Appendix (of the claims on appeal) are enclosed here in triplicate.

Additionally enclosed is a check for $165.00 for the small entity fee for the Appeal Brief.

Favorable reconsideration is respectfully requested in view of the following.

REAL PARTY IN INTEREST

The real party in interest is the appellant and inventor, Ralph L. Bass, as the subject application serial no. 09/721,131 has not been assigned.

RELATED APPLICATIONS

There are no other appeals nor interferences known to appellant or appellant's legal representative which will directly affect or be directly affected by or have a bearing on the Board's decision in the instant pending Appeal.

STATUS OF CLAIMS

By Amendment A, dated May 13, 2003, originally filed claims 1 – 22 were canceled and replaced with new claims 22 – 42, the latter being the presently pending claims on Appeal.

Claims 22 – 42 stand finally rejected under 35 U.S.C. §101 for lack of credible utility and under 35 U.S.C. §112, first paragraph, for lack of enablement.

Claim 35 stands finally rejected under 35 U.S.C. §112, first paragraph, for lack of enablement vis-a-vis transdermal administration.

STATUS OF AMENDMENTS AFTER FINAL REJECTION

No amendments were filed subsequent to Final Rejection.

SUMMARY OF INVENTION

The present invention, as defined in claim 22 (the only independent claim), is directed to administering a sodium chloride formulation to an HIV-infected person, where the amount of sodium chloride is more than the person's average daily intake but less than the toxic amount (defined as measured by TCLo and as measured by LD50), and periodically repeating the administration, thereby achieving alleviation of the HIV infection.

Support is at lines 3 – 23 of page 11 and line 19 of page 12 through line 2 of page 13 of appellant's specification.

The present invention, as defined in dependent claim 28 (wherein claim 28 depends back to dependent claim 27, which is directed the sodium chloride formulation being in a mixture with a form of potassium and which depends back to independent claim 22), is directed to the mixture of sodium chloride and potassium containing another ingredient selected from sulfur, phosphorus, zinc, manganese, iron, copper, chromium, iodine, magnesium, cobalt, selenium, or combinations thereof.

Support is at lines 6 – 14 of page 9 of appellant's specification.

The present invention, as defined in dependent claim 35, is directed to various types of administration of a solid formulation of the sodium chloride, namely oral, sublingual, buccal, transdermal, or a combination thereof.

Support is at lines 6 – 15 of page 5 of appellant's specification.

ISSUES

Issue 1. Are credible utility under 35 U.S.C. §101 and enablement under 35 U.S.C. §112, first paragraph, both lacking for independent claim 22 and claims 23 – 42 dependent back thereto, wherein claim 22 is directed to periodic administration of a sodium chloride formulation to an HIV-infected person in an amount more than the person's average daily intake but less than the toxic amount (defined as measured by TCLo and as measured by LD50) to achieve alleviation of the HIV infection, because the Laboratory Examples, which illustrate this periodic administration to achieve alleviation of the HIV infection, are prophetic?

Issue 2. Is enablement under 35 U.S.C. §112, first paragraph, lacking for transdermal administration as per dependent claim 35, wherein claim 35 is directed to various types of administration of a solid formulation of sodium chloride, namely oral, sublingual, buccal, transdermal, or a combination thereof, because there are no Laboratory Examples illustrating transdermal administration, although appellant's specification at lines 13 – 15 of page 5 indicates that a "good discussion of transdermal administration can be seen in U.S. Patent No. 5,016,652"?

Issue 3. Are credible utility under 35 U.S.C. §101 and enablement under 35 U.S.C. §112, first paragraph, both lacking for dependent claim 28 (which depends back dependent claim 27 which depends back to independent claim 22), wherein dependent claim 27 is directed the sodium chloride formulation being in a mixture with a form of potassium and claim 28 is directed to the mixture of sodium chloride and potassium containing another ingredient selected from sulfur, phosphorus, zinc, manganese, iron, copper, chromium, iodine, magnesium, cobalt, selenium, or combinations thereof, when recent research studies (mostly in vivo studies of HIV infected persons and a few in vitro studies) as published in various journals, report a correlation between the presence of nutrient deficiency for each of the nutrients recited in claim 28 and a decrease in the ability to inhibit HIV?

GROUPING OF CLAIMS

Claim 28 does not stand or fall together with the remaining claims 22 - 27 and 29 - 42.

ARGUMENT

Discussion of rejection of claims 22 - 42 under 35 U.S.C. §101 for lack of credible utility and for lack of enablement under 35 U.S.C. §112, first paragraph.

That sodium chloride, potassium, sulfur, phosphorus, zinc, manganese, iron, copper, chromium, iodine, magnesium, cobalt, and selenium, each of which is recited in one or more of appellant's claims, *are all nutrients required by the human body*, is to be kept in mind during the following discussion.

In the Final Rejection, the Examiner reiterated that the specification does not appear to show any working examples, but provides only prophetic examples of what would occur.

Additionally, the Examiner commented in the Final Rejection that the mechanism by which administration of sodium chloride results in reduction of HIV infection appears to be unsupported by evidence showing that the disclosed effective levels of NaCl would be sufficient to alleviate HIV.

Also, the Examiner stated in the Final Rejection that:

> Further as set forth in the prior Office Action, Merck brochure does appear to show that administration of sodium chloride as claimed would be effective in alleviating HIV infection or otherwise show that sodium chloride would act to disrupt the smaller HIV virus cells.

Appellant presumes that the Examiner has misstated what he meant and did not really intend to agree with appellant, since the Examiner has finally rejected the application. Presumably, the Examiner meant to state "...Merck brochure does *not* appear to show..." [emphasis supplied].

Appellant respectfully reiterates that the Examiner is ignoring two important legal premises of the U.S. Patent Laws:

1. There is no legal requirement for actual working examples; therefore, prophetic examples are acceptable. The reason is that the filing of an application constitutes a constructive reduction to practice of the invention. See, *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 224 U.S.P.Q. 409 (Fed. Cir. 1984).

2. There is no legal requirement for an inventor to set forth correctly, or even to know, how or why the invention works. See, *In Re Cortright*, 49 U.S.P.Q.2d 1464, 165 F.3d 1353 (Fed. Cir. 1999).

In connection with prophetic examples instead of working examples, Appellant respectfully reiterates the following vis-à-vis the distinction between an enablement issue under 35 U.S.C. §112, first paragraph, and a credible utility issue under 35 U.S.C. §101. See, both *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., supra,* and *In Re Cortright, supra.*

In connection with enablement under 35 U.S.C. §112, first paragraph, appellant respectfully reiterates that his prophetic Laboratory Examples and specification teach in great detail periodic administration of a certain amount of sodium chloride (more than the person's average daily intake, but less than the toxic amount which would kill the person, i.e., less than the amount of sodium chloride as measured by TCLo and as measured by LD50) to an HIV-infected person in order to alleviate the HIV infection.

Thus, the specification and prophetic examples are clearly sufficient to teach the person of ordinary skill in the art how to make and to use appellant's invention, without undue experimentation. As previously stated, *although appellant does not intend to be bound to any theory, appellant believes the following describes the how and the why, i.e., the mechanism, of his invention.*

As is well known to those of ordinary skill in the art of medicine, immunology, and the like, HIV virus cells have a relatively small size and human cells have a relatively large size.

To assist the Examiner in understanding this size difference, appellant forwarded the Merck brochure entitled "Livin'It" describing their drug CRIXIVAN® for treatment of HIV infection. The first two pages of the Merck brochure have a drawing that shows the smaller HIV virus cell in red attached to the larger human CD4 T-cell in blue. The Merck brochure also discusses how an HIV infection occurs. The HIV virus cell cannot replicate on its own because it does not have DNA but rather has only viral RNA. Thus, the small HIV virus cell attaches itself to the large human CD4 T-cell, replicating by using the DNA of the human CD4 T-cell.

Appellant *theorizes* that how and why his invention works is that the administration of sodium chloride beyond the average daily intake, but less than the toxic amount, should not disrupt the larger human cells, but should be enough to disrupt the smaller HIV virus cells. In other words, this particular amount of sodium chloride should result in a change in osmotic pressure that dehydrates the smaller HIV cells. They should thus be ruptured. Since the particular amount of sodium chloride is still less than the toxic amount, the particular amount should not be enough for rupturing the larger human body cells by a change in osmotic pressure resulting in dehydration.

Accordingly, the disruption/rupturing of the smaller HIV cells should cause them to be removed from the larger human cells, thereby alleviating the HIV infection.

Vis-a-vis the rejection under 35 U.S.C. §101, the Examiner stated in the Final Rejection that:

> Applicant indicates that the administration should result in circulating levels of NaCl within the range of about 0.05 μM to about 1.0 μM and that the extra amount of NaCl will disrupt the HIV virus. [However,] In Hrinda et al. (US Pat. 5,661,023) it is disclosed that NaCl concentrations as high as 1.4 M for prolonged periods, such as greater than 18 hours, only resulted in partial disassembling of HIV particles with dilution to 0.25 M being sufficient to prevent the same (Hrinda et al., Column 8, lines 51 - 68, Column 9, lines 1 - 12). Thus, it appears that the

effective amount of NaCl need to disrupt the HIV virus far exceeds what is disclosed and claimed as being the effective therapeutic range as well as the level of NaCl which would be considered to be safe in humans.

Appellant respectfully reiterates that the Examiner has misconstrued how the Hrinda et al. elution process for obtaining HIV particles relates to the present invention.

More specifically, Hrinda et al. inactivate HIV particles by beta-propriolactone (BPL) for about 18 – 24 hours, followed by flowing the BPL-treated HIV particles through a membrane to concentrate them. The concentrated HIV particles are then buffered with phosphate buffered saline (PBS), i.e., an aqueous solution of sodium chloride buffered with phosphate.

The PBS containing the HIV particles is then passed through columns filled with an anion exchange resin, such as TMAE FRACTOGEL®. The HIV particles attach to the TMAE FRACTOGEL® resin and are subsequently washed with an aqueous solution containing 0.1 - 0.55 M sodium chloride, buffered at a pH of 6 - 7.5.

The attached HIV particles are eluted off the resin using a higher sodium chloride concentration at 0.6 - 2 M, preferably 0.8 - 1.4 M, at the same buffered pH of 6 - 7.5. The eluted solution containing the retroviral particles, particularly HIV, is diluted to reduce the sodium chloride concentration to within the range of 0.05 - 0.25 M. Hrinda et al. state that this is to prevent the partial disassembling of the HIV-1 particles when exposed to the eluant's high sodium chloride concentration for prolonged periods of time, such as greater than 18 hours.

In other words, the sodium chloride concentrations noted by the Examiner, namely "concentrations as high as 1.4 M for prolonged periods, such as greater than 18 hours" that Hrinda et al. use in order avoid partially disassembling HIV particles, are concentrations for HIV particles floating in phosphate buffered aqueous sodium chloride.

In contrast, appellant's desirable circulating levels of sodium chloride within a range of about 0.05 μM to about 1.0 μM, as set out at lines 11 and 12 of page 12 of appellant's specification, are concentrations in human blood in a human body for HIV particles attached to human CD4 T-cells, not for HIV particles floating in phosphate buffered aqueous sodium chloride.

Appellant reiterates that one of ordinary skill in the art would conclude from the Merck brochure that an HIV cell attached to a CD4 T-cell in the human body would act differently from free HIV cells in phosphate buffered saline.

Appellant respectfully points out that the person of ordinary skill in the art will know that phosphate buffered saline solution is not coursing through the veins and arteries of the human body, nor are HIV cells free floating in the human body. Furthermore, that person will be aware of how HIV infects a person (for instance, the explanation in the Merck brochure).

As a result, the person of ordinary skill in the art would expect that HIV cells attached to CD4 T-cells in the human body should act differently from free HIV cells floating in phosphate buffered saline.

Accordingly, based upon current scientific understanding, the person of ordinary skill in the art would expect the claimed invention to function in the disclosed manner, as a treatment for HIV infection in a human, as is clearly illustrated by the prophetic examples and the specification. That person would not expect HIV particles attached to human CD4 T-cells to behave like the Hrinda et al. disclosure of HIV particles free floating in phosphate buffered aqueous sodium chloride.

However, it is also respectfully pointed out that Hrinda et al. did show the phosphate buffered saline removed the HIV cells from the TMAE FRACTOGEL® resin, and appellant does theorize that the particular amount of sodium chloride formulation will remove the HIV cells from the human CD4 T-cells. Thus, one could also argue in the alternative that the Hrinda et al. disclosure of HIV cells removed from TMAE FRACTOGEL® resin by phosphate buffered aqueous sodium chloride is supportive of appellant's theory of how and why his invention works.

In other words, one could argue that, based upon current scientific understanding, the person of ordinary skill in the art would expect the claimed invention to function in the disclosed manner, as a treatment for HIV infection in a human as is clearly illustrated by the prophetic examples and the specification because that person would be aware of how HIV infects a person (for instance, the explanation in the Merck brochure) and as a result, that person would expect HIV particles attached to human CD4 T-cells to behave like and be removed like the Hrinda et al. disclosure of HIV particles removed by a phosphate sodium chloride solution from TMAE FRACTOGEL® resin.

Nevertheless, it does not matter because what appellant stated with respect to the sodium chloride disrupting the HIV cells is only a theory of how the invention works. Appellant has no claims requiring that this mechanism is in fact how his invention works.

There is no legal requirement for an inventor to set forth correctly, or even to know, how or why the invention works. See, *In Re Cortright, supra.*

In summary vis-à-vis credible utility under 35 U.S.C. §101 and enablement under 35 U.S.C. §112, first paragraph, appellant respectfully reiterates the following with respect to *In Re Cortright, supra.*

Cortright's patent application, which eventually matured into her U.S. Patent No. 6,033,676, involved rubbing 8-hydroxy-quinoline sulfate, the active agent in Bag Balm®, into the scalp to treat baldness.

Cortright's claim 15 set out as claim requirements her **surmised theory** of how to use her invention. More particularly, claim 15 required offsetting the effects of lower levels of a male hormone being supplied by arteries to the papilla of scalp hair follicles with the active agent 8-hydroxy-quinoline sulfate, to cause hair to grow again on the scalp, by rubbing into the scalp the ointment having the active agent 8-hydroxy-quinoline sulfate 0.3 % carried in a petrolatum and lanolin base so that the active agent reaches the papilla.

The Court of Appeals specifically stated that it is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works. Thus, Cortright was not required to prove the cause of the hair growth, and claim 15 was not invalid for lack of utility under 35 U.S.C. §101.

However, Cortright's application had no laboratory data, either prophetic or actual, showing that the effects of lower male hormone levels had been offset by Bag Balm® nor even if Bag Balm® had reached the papilla, as required by the language in claim 15. Moreover, the "GENERAL" section at the end of her specification (see, line 50 of column 2 of U.S. Patent No. 6,033,676 to Cortright) started with "Applicant surmises..." prefacing the discussion of offsetting lower male hormone levels by reaching the papilla. Hence, her specification clearly set out that this mechanism was only a theory, not a teaching of how to use. Thus, claim 15 was invalid for not satisfying the how to use requirement of 35 U.S.C. §112, first paragraph.

In contrast, the present appellant's claims do **not** set out as claim requirements appellant's **surmised theory** of how to use his invention by the sodium chloride disrupting the relatively smaller HIV cell, and removing it from the relatively larger human cell.

Thus, there is no need for working examples, nor anything else, for appellant to prove how his invention works.

The Examiner noted that Cortright had working examples.

Appellant respectfully points out that Cortright's working examples were for her other claim which issued in her U.S. Patent No. 6,033,676, not for rejected claim 15.

The Examiner also stated that a method of alleviating HIV infection by administration of sodium chloride is inherently suspect.

Appellant respectfully points out that treating HIV infection was once considered an inherently unbelievable undertaking, but since then, treatments for HIV infection have gained acceptance, and both AZT (zidovudine) and 3TC (lamivudine) are recognized as effective for treating HIV infection. Similarly, the Court of Appeals in *In Re Cortright, supra* noted that treating baldness was once considered an inherently unbelievable undertaking, but since then, treatments for baldness have gained acceptance, and ROGAINE® (minoxidil) and PROPECIA® (finasteride) are recognized as effective for treating baldness.

Regardless, appellant respectfully submits that it is unlikely that the person of ordinary skill in the art would base a conclusion of existence of credible utility or lack of credible utility on whether HIV cells in the body behave like HIV cells in phosphate buffered saline.

The Examiner now in the Final Rejection had placed reliance on *Newman v. Quigg*, 11 USPQ2d 1340, 1345 (CAFC 1989), which was referred to by the Court of Appeals in *In Re Cortright, supra*, for the proposition that when a claimed invention lack utility, the specification cannot be said to have taught one of ordinary skill in the art to use the invention.

However, appellant respectfully points out that the Examiner has ignored that Newman's claimed invention was for a machine that has a higher energy output than the energy input.

As is well know, patent applications directed such machines are in the same class as patent applications directed to perpetual motion machines. The US PTO has deemed such inventions to be *per se* inherently suspect, and hence, the US PTO always requires models. Newman failed to produce a model, and so the patent application was rejected.

In contrast, patent applications directed to a new medical use of a known composition, where the patent application has prophetic examples, are *not* deemed by the US PTO to be *per se* inherently suspect.

As previously discussed, appellant conducted further research and found various recent research studies (mostly in vivo studies for HIV-infected persons and a few in vitro studies) as published in various journals, Titles and also abstracts and/or descriptors of which were

previously forwarded to the Examiner. These research studies have reported a correlation between a decrease in the ability of HIV-infected persons to inhibit HIV and the presence in these HIV-infected persons of a deficiency for various nutrients, such as sulfur, phosphorus, zinc, manganese, iron, copper, chromium, magnesium, cobalt, and selenium. (The research studies do not address the nutrients, sodium chloride and potassium.)

Appellant respectfully notes that in the Final Rejection, the Examiner has repeated that of the 38 research studies, some were not prior to the November 22, 2000 filing date of the present application, and presented a discussion in the Final Rejection of each of the 38. The Examiner did this even though appellant has already withdrawn those of the 38 that were not prior to the November 22, 2000 filing date (references 8, 21, 30, and 31 were withdrawn), and remaining are references 7 – 9 and 20 - 38. The Board is requested to direct the Examiner to cease making comments in this regard.

The Examiner is correct vis-à-vis that none of these remaining references 7 - 9 and 20 - 38 mentions iodine. However, the Examiner indicated uncertainty vis-à-vis references 8, 21, 30, and 31, as these have a Title but no abstract, and the Examiner believes that the Title does not appear sufficient. Appellant respectfully notes that for all references there are descriptors. Thus, those few references that are absent the abstract indeed have descriptors as well as a Title, not just a Title.

Appellant respectfully submits that the person of ordinary skill in the art would know that sodium chloride is a nutrient and so are potassium, sulfur, phosphorus, zinc, manganese, iron, copper, chromium, iodine, magnesium, cobalt, and selenium. Also, the person of ordinary skill in the art would be aware of many, if not all, of these research studies 7 - 9 and 20 - 38. Thus, on the basis of those research studies, the person of ordinary skill in the art would conclude credible utility exists for appellant's invention.

Also in the Final Rejection, the Examiner cited *Ex parte Sudilovsky*, 21 USPQ2d 1702, 1705 (Bd Pat Appl & Int 1991) for the proposition that although lack of working examples is not controlling determining whether a disclosure meets the enablement requirement of 35 U.S.C. §112, when a patent applicant chooses to forego exemplification and bases utility on broad terminology and general allegations, he runs the risk that unless one with ordinary skill in the art would accept the allegations as obviously valid and correct, the Examiner may, properly, ask for evidence to substantiate them.

With regard to 35 U.S.C. §112, first paragraph, appellant respectfully points out that he did not base utility on broad terminology and general allegations, in contrast to Sudilovsky.

Rather, appellant's specification and prophetic laboratory Examples teach in great detail periodic administration of a certain amount of NaCl (more than the person's average daily intake, but less than the toxic amount which would kill the person, i.e., less than the amount of NaCl as measured by TCLo and as measured by LD50) to an HIV-infected person in order to alleviate the HIV infection. Appellant's Laboratory Examples are very detailed and specific about determining the average daily intake and the amounts and frequency of NaCl to be administered to the person.

On the other hand, Sudilovsky's application merely had broad terminology and general allegations of a "treatment effective amount" of the angiotensin converting enzyme inhibitor alone or in combination with a calcium channel blocker, for inhibiting tardive dyskinesia in a mammalian specie. There are no details on the amounts and frequency of the angiotensin converting enzyme inhibitor to be administered.

The Examiner stated in the Final Rejection that:

> Contrary to Applicant's assertions, the specification in Sudilovsky was highly detailed (Sudilovsky at pg. 1705).

Appellant respectfully points out that once again the Examiner is quoting out of context, as the Court at page 1705 of Sudilovsky refers to the detailed specification being with respect to a description of compounds stated to be known ACE inhibitors and how to make tablets and solutions for injection.

As appellant stated before, there are no details in Sudilovsky on the amounts and frequency of the inhibitor to be administered for inhibiting tardive dyskinesia. Sudilovsky only has a generalization about a treatment effective amount. In contrast, appellant's Laboratory Examples are very detailed and specific about determining the average daily intake and the amounts and frequency of NaCl to be administered.

Accordingly, appellant respectfully requests the Board to instruct the Examiner to withdraw the rejection of claims 22 - 42 under §101 and under §112, first paragraph.

Discussion of separate patentability for dependent claim 28, which is included in the Examiner's rejection of claims 22 - 42 under 35 U.S.C. §101 for lack of credible utility.

The above arguments vis-à-vis both *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co., supra,* and *In Re Cortright, supra,* are incorporated here by reference, and appellant further points out the following vis-à-vis dependent claim 28.

The Examiner stated that:

> Further as set forth in the prior Office Action, Merck brochure does [*sic*, not] appear to show that administration of sodium chloride as claimed would be effective in alleviating HIV infection or otherwise show that sodium chloride would act to disrupt the smaller HIV virus cells. As such, there is no evidence that one of ordinary skill in the art would expect from Hrinda et al. in view of the Merck brochure that administration of the claimed amounts of sodium chloride would be effective in alleviating HIV infection.

Would one of ordinary skill in the art base a conclusion of credible utility on whether HIV cells in the body behave like the Hrinda et al. disclosure of HIV cells in PBS?

No.

One of ordinary skill in the art would also be aware of recent research studies (mostly in vivo studies for HIV-infected persons and a few in vitro studies) as published in various journals (copies of Titles and also abstracts and/or descriptors of such publications previously submitted) that report a correlation between a decrease in the ability to inhibit HIV and the presence in HIV-infected persons of nutrient deficiency for many of the nutrients (sulfur, phosphorus, zinc, manganese, iron, copper, chromium, magnesium, cobalt, and selenium) that appellant has recited in his dependent claim 28.

For instance, Droege et al., "Improvement of Immune Functions in HIV Infection by Sulfur Supplementation: Two Randomized Trials", Vol. 78, No. 1, *Journal of Molecular Medicine*, pp. 55 - 62 (2000) shows administration of sulfur to HIV-infected persons alleviated the HIV infection; and Graham et al., "Relationship of Serum copper and Zinc Levels to HIV-Seropositivity and Progression to AIDS", Vol. 4, No. 10, *Journal of Acquired Immune Deficiency Syndrome*, pp. 976 - 980 (1991) shows many HIV-infected persons had zinc and copper deficiencies. The Examiner and the Board are invited to browse through all of the research studies.

Thus, one of ordinary skill in the art would conclude that appellant's invention as per dependent claim 28 for having the mixture of sodium chloride and potassium that is periodically administered to an HIV-infected person contain one of more of various nutrients (sulfur, phosphorus, zinc, manganese, iron, copper, chromium, iodine, magnesium, cobalt, and/or selenium) would be credible for treatment of HIV, and hence that person would conclude that credible utility is most certainly present for dependent claim 28.

Accordingly, appellant respectfully requests the Board to instruct the Examiner to withdraw the rejection of claim 28 under §101 and §112, first paragraph.

Discussion of rejection of claim 35 under §112, first paragraph, for the specification not enabling transdermal administration.

The Examiner stated vis-à-vis the rejection of claim 35 that the specification does not provide enablement for transdermal administration. As support, the Examiner cited the journal article entitled "Salt Water Soaking Possible Alternative Psoriasis Treatment" from *Dermatology Times*, which contains a statement that there was no transdermal uptake of sodium chloride from a *salt bath*.

Appellant respectfully reiterates that the Examiner appears not to understand transdermal administration versus topical administration, although the Examiner is correct with respect to what the *Dermatology Times* journal article states.

Soaking in a salt bath only provides for *topical administration* of sodium chloride. Thus, no transdermal uptake of sodium chloride from a salt bath is what is expected.

Previously, the Examiner noted appellant has no Laboratory Examples illustrating transdermal administration. As explained exhaustively above, there is no requirement for Laboratory Examples. It is only required that the specification teach the person of ordinary skill in the art how to make and how to use the invention, without undue experimentation.

Appellant respectfully reiterates that, as well known to the person of ordinary skill in the art, transdermal administration is effected with a skin patch containing various chemicals, in addition to the agent that it is desired to administer transdermally. Skin patches for transdermal

administration of various agents are well known, and appellant is not claiming to have invented transdermal skin patches.

Rather, appellant clearly provided enablement by the reference on lines 13 - 15 of page 5 of his specification vis-a-vis an explanation of transdermal administration being in U.S. Patent No. 5,016,652. Thus, how to make and how to use skin patches for transdermal administration can be readily ascertained from appellant's specification, without undue experimentation.

The Examiner mentioned in the Final Rejection that:

> The specification does [*sic*, not] appear to show how a skilled artisan would administer sodium chloride in the upper GI tract transdermally when there is no skin in the upper GI tract.

As appellant indicated with "[*sic*, not]", appellant presumes that the Examiner has misstated what he meant and did not really intend to agree with appellant, since the Examiner has finally rejected the application.

As noted above, the Examiner does not comprehend what transdermal administration is. As is well known to the person of ordinary skill in the art, once something is transdermally administered, that thing is in the patient's blood stream and thus all over the patient's body, including the upper GI tract.

Therefore, appellant respectfully requests the Board to instruct the Examiner to withdraw the rejection of claim 35 under the first paragraph of §112.

CONCLUSIONS

Appellant respectfully submits that the present invention as claimed is enabled by the specification in such a way as to convey to the person of ordinary skill in the art that appellant had possession of the claimed invention and in such a way as to teach a person of ordinary skill in the art how to make and/or how to use the invention without undue experimentation. The filing of the application with prophetic Laboratory Examples is a constructive reduction to practice. Accordingly, appellant respectfully requests the Board to instruct the Examiner to withdraw the rejection of claims 22 - 44 under §112, first paragraph.

Moreover, appellant respectfully submits that the present invention as claimed has credible utility, as there is no requirement that an inventor set forth, or know how or why the invention works. Thus, appellant respectfully requests the Board to instruct the Examiner to withdraw the rejection of claims 22 - 44 under §101.

Also, appellant respectfully submits that transdermal administration is clearly enabled. Hence, appellant respectfully requests the Board to instruct the Examiner to withdraw the rejection of claim 35 under the first paragraph of §112.

Appellant respectfully submits that the present application is in proper condition for allowance and respectfully requests the Board to instruct the Examiner to issue an official notification of allowance.

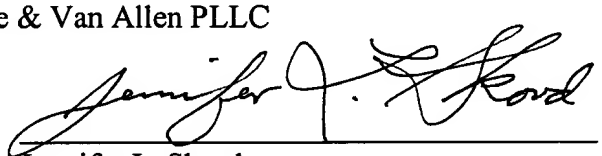
DEPOSIT ACCOUNT

Although a check in the amount of $165.00 is enclosed for the fee for the Appeal Brief and it is believed that no further fee is due, the Commissioner is hereby authorized to charge any deficiencies of payment associated with this Communication, or to credit any overpayment, to Deposit Account No. 13-4365.

Respectfully submitted,

Moore & Van Allen PLLC

Date: June 25, 2004

By: 

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JLS/js

Enclosures:
Check in the amount of $165 (small entity) for fee for Appeal Brief
In triplicate, Appeal Brief and its Appendix (of claims pending on Appeal)

APPENDIX
(Claims on Appeal for Application Serial No. 09/721,131)

22. A method for providing sodium chloride to a human having HIV infection by administering to the upper gastro-intestinal tract of the human a selected amount of a formulation of sodium chloride, said method comprising:

(a) administering the sodium chloride formulation to the human's upper gastro-intestinal tract so as to introduce the sodium chloride formulation to the metabolism of the human, wherein the amount of the sodium chloride in the sodium chloride formulation administered is (i) sufficient to provide more sodium chloride than the human's average daily intake for sodium chloride, as determined after monitoring the human for about 1 month, (ii) less than a toxic amount measured by TCLo, the dosage for oral consumption that is the lowest dosage of sodium chloride that has produced toxic side effects in humans, and (iii) less than a toxic amount measured by LD50, the dosage of sodium chloride that is lethal for 50% of the human population;

(b) periodically repeating (a), so as to administer a therapeutically effective amount of the sodium chloride formulation to the human's metabolism; and

(c) achieving alleviation of the HIV infection.

23. The method of claim 22, wherein the sodium chloride formulation is free of having other medicaments incorporated therewith for treatment of HIV infection.

24. The method of claim 22, wherein steps (a) and (b) are accomplished at least once per day.

25. The method of claim 22, wherein the amount of the sodium chloride formulation administered is sufficient to provide at least about 250 mg per day more sodium chloride than the human's average daily intake for sodium chloride, as determined after monitoring the human for about 1 month.

26. The method of claim 25, wherein the amount of the sodium chloride formulation administered and the average daily intake for sodium chloride provide at least 7500 mg/day of sodium chloride.

27. The method of claim 22, wherein the sodium chloride formulation is a mixture with a form of potassium in a weight ratio amount of Na:K up to about 1:1.

28. The method of claim 27, wherein the mixture contains up to about 20% by weight of another ingredient selected from the group consisting of S, P, Zn, Mn, Fe, Cu, Cr, I, Mg, Co, Se, and combinations thereof.

29. The method of claim 22, wherein the sodium chloride formulation is free of having other mineral salts incorporated therewith except for trace amounts thereof.

30. The method of claim 22, wherein the sodium chloride formulation is in a form selected from the group consisting of a solid formulation of sodium chloride and a solution formulation of sodium chloride.

31. The method of claim 30, wherein the solid formulation contains from about 55% to about 100% of sodium chloride.

32. The method of claim 31, wherein the solid formulation contains from about 75% to about 100% by weight sodium chloride.

33. The method of claim 30, wherein the solid formulation of sodium chloride is free of having a carrier incorporated therewith.

34. The method of claim 30, wherein the solid formulation of sodium chloride is selected from the group consisting of a tablet, a powder, and a combination thereof.

35. The method of claim 30, wherein administration of the solid formulation of sodium chloride is administration selected from the group consisting of oral, sublingual, buccal, transdermal, and a combination thereof.

36. The method of claim 30, wherein the solution formulation of sodium chloride contains at least about 2% by weight sodium chloride.

37. The method according to claim 30, wherein the solution formulation of sodium chloride is aqueous.

38. The method according to claim 30, further including a flavoring in the solution formulation of sodium chloride to improve palatability.

39. The method according to claim 38, wherein the flavoring is selected from the group consisting of sugar, coffee, beer, wine, whiskey, fruit juice, milk, soda, mint, and combinations thereof.

40. The method of claim 30, wherein administration of the solution formulation of sodium chloride is administration selected from the group consisting of oral, gavage, and a combination thereof.

41. The method according to claim 22, wherein the administration to the upper gastro-intestinal tract is by way of a portion of the upper gastro-intestinal tract selected from the group consisting of a mouth, an esophagus, a stomach, a duodenum, and a combination thereof.

42. The method according to claim 22, further including a minor amount of another ingredient selected from the group consisting of potassium chloride, potassium carbonate, potassium protein complexes, potassium phosphate, sodium carbonate, sodium protein complexes, sodium phosphate, and combinations thereof, wherein the total minor amount of said other ingredients is less than about 45% by weight, based on the weight of the sodium chloride.